March 17, 2000

Jane A. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

It has been brought to our attention that the Food and Drug Administration (FDA) intends to take actions that will have a direct impact on an ongoing FDA rulemaking that we believe could be detrimental to small business interests. FDA's planned actions may violate the Freedom of Information Act (FOIA), and may also undermine an important public trust that is placed in FDA to act in a fair and scientific manner to advance the interests of public health. We respectfully request that FDA reconsider its planned course of action, discussed below, and that FDA adopt an alternative plan of action that will preserve the interests of the law and of public health.

Background

As you may recall, the Office of Advocacy filed extensive comments on FDA's June 4, 1997 proposed rule regarding dietary supplements containing ephedrine alkaloids. Our comments focused on small business concerns and FDA's lack of compliance with the Regulatory Flexibility Act (RFA) and other applicable laws protecting small business interests. In particular, Advocacy expressed concerns over the apparent lack of valid scientific evidence to support the proposed restrictions on these dietary supplements. This point was of extreme importance given that the proposed restrictions, if they had been put into effect, would have banned the major market for these products use as an aid to weight loss with profound effect on the livelihoods of hundreds of thousands of independent distributors and on consumers who rely on these products to stay healthy.

Subsequent to our comments, the General Accounting Office (GAO) conducted an audit of FDA's proposed rule and confirmed what experts outside the agency had found in their analysis that there was an inadequate basis for FDA's duration limits for these products (on which FDA's proposed ban on marketing for weight-loss was based), and that FDA had based its proposed serving limits on just thirteen adverse event reports (AERs). FDA, in response to the findings in the GAO report, stated that they did not base dose limits on only thirteen reports even though FDA stated explicitly in the preamble of the proposed rule that those thirteen reports were the basis for the limits.

The Industry's FOIA Request

FDA's proposal was based on AERs that had been submitted to FDA through June of 1997. After it became clear to industry that the rulemaking might take a considerable amount of time, industry representatives apparently attempted to gain access to the new AERs on ephedra products that were submitted to FDA after June 1997. Several important purposes were to be achieved through compilation and evaluation of these AERs.

First, industry needed the AERs to confirm what their own records were showing – that the national standard the industry had established was causing a substantial decrease in AERs despite soaring sales of these products. Industry established voluntary trade standards (e.g., the American Herbal Products Ephedra Trade Recommendation), and had these standards incorporated into state laws. In 1997, industry standards were adopted as law in Ohio and Washington and most recently, in Hawaii and Michigan. The major industry trade associations claim that their members, representing the vast majority of the major supplement companies, now comply with the national standard for these products, which includes per serving and daily intake limits of 25 mg and 100 mg, a comprehensive warning statement including a recommendation against use by minors, and a prohibition on marketing for herbal "highs."

Second, industry needed to monitor the reports to respond to press reports of serious adverse events that were alleged to be connected to the consumption of Ephedra products. Finally, individual companies needed to obtain the reports for their own analysis to further evaluate their products to assure safety, to monitor product and ingredient quality, and to assure independent distributors that press reports were not accurate.

FDA is required by law to respond to FOIA requests within 20 days. The industry claims that it has been two or more years since repeated FOIA requests for new Ephedra AERs have been filed. However, FDA has only said that it lacks the resources to respond to the FOIA requests.

Most recently, FDA has said that it plans to withdraw the proposed dose and duration limits for these products and to release the AERs to the public in the near future. In itself, this is good news. However, the industry has been told that FDA simultaneously plans to publish in the *Federal Register* a detailed scientific analysis of the reports, as well as a new analysis of the scientific literature that relates to these products.

The industry has expressed concern that the agency on the one hand lacks the resources to conduct a simple purging of the reports to remove confidential patient information, while on the other had, FDA has the resources to conduct a thorough medical and scientific evaluation of the same AERs. The industry is also concerned that FDA is purposefully manipulating the system and withholding information from the public and the industry in order to redeem the agency's reputation. Advocacy does not believe this to be the case; however, FDA is losing a great deal of good will within the industry because of its actions.

The release of the reports with a negative FDA analysis could eliminate the market for these products without FDA ever needing to continue its rulemaking. Further, small business is concerned that if FDA releases the AERs with an analysis, the agency will not put the AERs in proper context; that is, FDA will not inform the public what the real risk of any particular event is, will not inform the public of the enormous numbers of individuals consuming these products, and will not inform the public that the number of events has dropped significantly in the past years despite soaring sales. FDA did not attempt to frame the AERs that were released with its June 1997 proposal in the proper context, hence the concern as to whether FDA intends to do so now.

The industry would like FDA to provide an opportunity to evaluate the reports before FDA characterizes them to the press and the public. Although Advocacy has no statutory authority to force FDA to comply with the industry's FOIA requests, in the spirit of fairness and cooperation, we would ask that FDA make a serious effort to comply. Moreover, the perceived mistrust the agency has apparently generated over the past couple of years could possibly be alleviated if the agency would release the AERs, and provide industry with ample time to review these reports before FDA holds a public forum on these products. An FDA analysis that is released after all of the available information is carefully considered, including the views and analysis of interested members of the public, including small business, will be much more credible than any agency analysis that is released prior to public review and comment.

Advocacy would be happy to meet with you if you wish to discuss this matter further. In the meantime, do not hesitate to call if you have any questions.

Sincerely,

Jere W. Glover
Chief Counsel for Advocacy

Shawne Carter McGibbon
Assistant Chief Counsel for Advocacy